



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG - 4 1999

NADA 141-108

Andrew T. Palmeter, D.V.M.
Associate Director, Regulatory Affairs
Fort Dodge Animal Health
Cyanamid Agricultural Center
P.O. Box 400
Princeton, NJ 08543-0400

Dear Dr. Palmeter:

We refer to the full-page promotional piece for EtoGesic™ (etodolac) tablets (NADA 141-108) that appeared in the May/June 1999 Burns Catalog.

You may recall that in a September 4, 1998 meeting with Fort Dodge, CVM pointed out several deficiencies in your product's promotional material and discussed the extent of their violations with the promotion and advertising regulations in fair detail. Lack of fair balance is still an issue with the promotional piece in question. Again, the safety of EtoGesic™ has been overemphasized while side effects have been minimized. In addition, there should be full prescribing information or package insert included as required under 21 CFR part 201.105(d)(1). The clinical significance of COX-2 selectivity with specific targeting of pain and reduced potential for gastrointestinal and renal side effects has not been proven. COX-2 was discussed in the September 4, 1998, meeting and should not have appeared in the Burns Catalog with this promotional item. The statement, "Approved for use in all breeds" is misleading and unsubstantiated. The drug was only tested in beagle dogs. The statement, "Proven safe for long term use," is also misleading. Safety studies were only conducted for one year. While it is true that there is no restriction on duration of treatment, the promotional piece implies that EtoGesic™ is absolutely safe for any duration.

We wish to remind you that promotion of your product in Burns catalog which is false, lacking in fair balance or otherwise misleading (21 CFR 202.1(e)(5)(ii)) further causes your product to be misbranded under Section 502(a) of the Act. We request that you discontinue promotion of your product in Burns catalog and in the future you or any body acting in your firm's behalf should promote only in accordance with the promotion and advertising regulations.

Please inform us of your intentions as soon as possible, or in any event within 30 days of receipt of this letter. If you have any questions, you may contact us at (301) 827-6642.

Sincerely,

Mohammad I. Sharar, DVM, MSc.
Team Leader Marketed Product Scientific
And Regulatory Review Team II, HFV-216
Division of Epidemiology and Surveillance
Center for Veterinary Medicine